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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,303	04/19/2004	Nobukazu Onishi	Q81147	9815

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2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,303	ONISHI ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,17-19,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,17-19,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *all*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15, 17-19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuhashi et al. US 4,939,239, in view of McGinley et al. US 5,462,761.

Matsuhashi teaches a preparation comprising hyposensitization agent covalently bond to a saccharide having an average molecular weight in the range of 500-10,000,000 useful for the treatment of allergy, such as cedar pollen allergy (column 1, lines 54 through column 2, lines 1-24). Matsuhashi teaches saccharide helps prevent an anaphylaxis and facilitates the preparation of a more effective preparation for the treatment of allergy (column 2, lines 20-24). Saccharide includes glucomannan (id).

The preparation can be formulated into tablet, troche, ophthalmic solution, intranasal nebula, cream and lotion (column 3, lines 58-64).

Matsuhashi does not explicitly teach the average particle size of glucomannan.

McGinley teaches the use of glucomannan in food products (abstract; and column 3, lines 8-53). Glucomannan derived from konjac, and intimately mixed with microcrystalline cellulose to obtain aggregate particles having average particle size of 0.1-100 μm (column 2, lines 1-65). Thus, it would have been obvious to one of ordinary skill in the art to modify the preparation of Matsuhashi using the particle in view of the teaching of McGinley, because McGinley teaches the use of glucomannan having small particle size is known in the art.

It is noted that the cited references do not explicitly teach the fiber content of the glucomannan. However, absent of evident to the contrary, the burden is shifted to applicant to provide evident that the glucomannan taught by the cited references do not have the fiber content of 95% or more. This is because the cited references teach glucomannan obtained by a similar method disclosed by the present invention, namely, purified glucomannan (see for example McGinley at column 2, lines 64). Furthermore, Matsuhashi teaches the use of glucomannan for the same purpose, namely, glucomannan useful for the treatment of allergy, such as cedar pollen allergy (column 1, lines 54 through column 2, lines 1-24). Matsuhashi further teaches saccharide helps prevent an anaphylaxis and facilitates the preparation of a more effective preparation for the treatment of allergy (column 2, lines 20-24). Accordingly, the burden is shifted to applicant to show any unexpected and/or unusual results over the fiber content.

Response to Arguments

Applicant's arguments filed 12/22/06 have been fully considered but they are not persuasive.

Applicant argues that the present claims recite glucomannan which is not covalently linked to an allergen. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., glucomannan which is not covalently linked to an allergen) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, Matsuhashi is cited in view of McGinley. McGinley teaches Glucomannan derived from konjac, and intimately mixed with microcrystalline cellulose to obtain aggregate particles having average particle size of 0.1-100 μm (column 2, lines 1-65).

Applicant argues that the analysis to combine Matsuhashi and McGinley is incorrect, because Matsuhashi teaches away from using a saccharide that is not covalently bonded to an allergen. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170

USPQ 209 (CCPA 1971). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues that claims 15 and 19 are now recited the limitation of the glucomannan having a dietary fiber content of 95% or more, which was recited in original claims 16 and 20. However, the burden is shifted to applicant to provide evident that the glucomannan taught by the cited references do not have the fiber content of 95% or more. This is because the cited references teach glucomannan obtained by a similar method disclosed by the present invention, namely, purified glucomannan (see for example McGinley at column 2, lines 64). Furthermore, Matsuhashi teaches the use of glucomannan for the same purpose, namely, glucomannan useful for the treatment of allergy, such as cedar pollen allergy (column 1, lines 54 through column 2, lines 1-24). Matsuhashi further teaches saccharide helps prevent an anaphylaxis and facilitates the preparation of a more effective preparation for the treatment of allergy (column 2, lines 20-24). Accordingly, the burden is shifted to applicant to show any unexpected and/or unusual results over the fiber content.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Patent Examiner
Art Unit 1615